Site Specific Applications

Research Ethics & Governance Unit
Office of Health and Medical Research
• Completed simultaneously with the NEAF

• Need to start negotiations regarding other supports or approvals as soon as HREC submission is made.

• Not sent to RGO until HREC approval granted.

• Addresses *site specific* requirements

• New version about to be released
So why is a new version needed?

• Impact of SERP and HoMER

• Changes to Federal and State legislation

• Changes to processes within the jurisdictions
Section 1: Project details

- HREC Application Reference Number
- Name of HREC reviewing the research project
- Name of site
- Single or multi centre
- Other details automatically populated from NEAF.
- Ability to edit text
Section 2: Description of Project

- Nothing new here.

Hooray!
Section 3: Study Type, NHMRC Group and Field of Research Categories

• New selections in “study type”
• This section added to SSA because
  – Is required for report to Chief Scientist
  – Feeds data into DORA
  – Previously, HREC administrator or other person decided which category
• Now the researcher must select most appropriate category
**Section 3: Study Type, NHMRC Group and Field of Research**

- Study type, NHMRC Group and Fields of Research categories

3.1 Please select study type (one only) **Mandatory field**

<table>
<thead>
<tr>
<th>Clinical Research</th>
<th>Clinical Research</th>
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<tbody>
<tr>
<td>Clinical trial of a drug / device</td>
<td>Clinical trial of a drug</td>
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<td>First time in human clinical trial /</td>
<td>Clinical trial of a device</td>
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<tr>
<td>First time in patient clinical trial</td>
<td>Other clinical trial</td>
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<tr>
<td>Health research / Social science</td>
<td>First time in human clinical trial /</td>
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<td></td>
<td>First time in patient clinical trial</td>
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<tr>
<td>Other</td>
<td>Health research / Social science</td>
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<td></td>
<td>Other</td>
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</tbody>
</table>
3.2 Please select the NHMRC Group and Field of Research from the drop down boxes. Mandatory fields.

The ABS fields have been removed from the new SSA. Only the NHMRC groups are required.
Section 4: Researchers Details.
• Demographics unchanged.
• New information relates to credentialing.

• *Medical staff only:*
  • Have you been credentialed at a Queensland Health District?   Yes  No  N/A
  • What is the expiry date? (___/___/____)
  • Does the credentialing scope of clinical practice cover all the relevant aspects of the investigator’s participation in this study   Yes  No
  • How will this deficit in credentialing be addressed?
Contact Person at the Site

• Only change is additional information regarding who the contact person may be

• *The PI will be responsible for ensuring there is a Contact Person at the site who will liaise with the District/site research governance personnel. The contact person may be the PI or a person nominated by the PI however they must be located at the site.*
Q8: Queensland Health policy on access to confidential information held by the Department.

- The current questions:
  - **8.1** Does the project require access to Confidential Information held by Queensland Health? Yes No
  - **8.2** If so, have you consulted with the data custodian to determine whether the data you require is collected and accessible? Yes No
The New Q8:

- **8.1** Have you consulted with the data custodian/s regarding access to Confidential Information held by Queensland Health, to determine whether the data you require is collected and accessible?  
  - Yes  
  - No

- Please consult with the relevant data custodian to determine whether the data you require is collected and accessible:  
The current PHA supporting information:

- Details of the *Public Health Act 2005* research provisions for access to confidential information may be found on the Queensland Health Research and Ethics Advisory Unit site [http://www.health.qld.gov.au/ohmr/html/regu/ace
The NEW PHA supporting information:

Studies requiring PHA approval
Chapter 6 Part 4 of the Public Health Act 2005 (PHA) establishes the process for accessing health information held by Queensland Health for approved research projects. The PHA requires researchers to apply to the Director-General of QH or his/her delegate, for access to health information held by QH.

The PHA applies to all researchers (internal and external to Queensland Health) who are undertaking research using identifiable or potentially re-identifiable health information for which the researchers are unable to obtain participant consent to use their personal or identifying information for a clearly specified research study.

Details of the Public Health Act 2005 research provisions for access to confidential information may be found on the Queensland Health Research and Governance Unit site http://www.health.qld.gov.au/ohmr/html/ręgui/aces_conf_hth_info.asp.

8.2 Does this study require PHA approval?  Yes  No

8.3 PHA approval letter attached  Yes  No

Explain why the PHA approval letter is not attached. Approval to commence the study can not be granted until PHA approval is received.
Q9: CaSS Information

• The current statement is simply this:
• For use of human tissue that is held by Queensland Health – Contact Research Office in Clinical and Statewide Services or visit http://www.health.qld.gov.au/qhcss/research.asp
The New Q 9: CaSS Information

• Authorisation to Proceed from the Chief Executive Officer CaSS is required for any research project using information for which CaSS (including Pathology Queensland, Forensic and Scientific Services, Medication Services Queensland and other branches of CaSS) is the data custodian and for any research project involving CaSS staff or resources. This includes but is not limited to .... etc

• The CaSS Coordination Planning and Research Unit (CPRU) is responsible for managing CaSS approval process and will assist researchers with this process.

• For use of human tissue that is held by Queensland Health – Contact Research Office in Clinical and State-wide Services or visit http://www.health.qld.gov.au/qhcss/research/default.asp
Questions Relating to CaSS

• **9.1** Is approval from Clinical and Statewide Services (CaSS) Research Committee required?  
  Yes ☐  No ☐

• **9.2** CaSS approval letter attached  
  Yes ☐  No ☐

  Explain why the CaSS approval letter is not attached and contact CPRU if you have not obtained CaSS approval.

• **9.3** Does this study require access to Pathology Queensland specimens?  
  Yes ☐  No ☐
But wait ... There's more!

- **9.4** Have you consulted directly with Pathology Queensland regarding access?  
  Yes ☐  No ☐

- Please consult with Pathology Queensland re access to the required specimens prior to requesting CaSS approval.

- **9.5** Does this study require Pathology Queensland tests or services?  
  Yes ☐  No ☐
• **9.6** Pathology Queensland quote and approval attached? Yes □ No □

• Explain why the Pathology Qld quote and approval is not attached.
Q 10: Research Involving Access to Coronial Material

• 10.1 Does this study require access to Coronial Material? Yes □ No □

• 10.2 Has this study received approval from Queensland Health Forensic and Scientific Services Human Ethics Committee? Yes □ No □

• This study must be referred back to the QH FSS HEC for approval.

• Q10.3 Forensic Services HREC Approval Letter.
• Q10.4  State Coroner approval
• Q10.5:  State Coroner approval letter
• Q10.6:  Access to Coronial Documents
• Q10.7:  Approval as “Genuine Researcher”
Q 11: Research involving adults with impaired capacity to consent

- Change in name of Guardianship Administration Tribunal

- Where a person is over the legal age of consent but is unable to give consent, written application to the Queensland Civil and Administrative Tribunal (QCAT) must be undertaken.
- For further information please go to the Queensland Civil and Administrative Tribunal:
12. Research involving ATSI Peoples including Coincidental Recruitment

• 12.1 Have the researchers had relevant community engagement with Aboriginal and Torres Strait Islander individuals, communities and/or organisations in conceptualisation, development and approval, data collection and management, analysis, report writing and dissemination of results for this study, relevant to this site? Yes  No

• 12.2 Address the extent to which the application fulfils the criteria of Reciprocity and community engagement; Respect; Equality; Responsibility; Survival and protection; and Spirit and integrity in relation to research into the health of Indigenous Australians at this site.
• Q13: Clinical Trials

• 13.1 Please select the study phase (one only)

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<tr>
<th>Phase</th>
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<td>Phase I clinical trial</td>
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<td>Phase III clinical trial</td>
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<tr>
<td>Phase IV / post marketing surveillance</td>
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13.2 Research conducted under the Clinical Trial Notification (CTN) or Clinical Trial Exemption (CTX) schemes?

• Under the Clinical Trial Notification (CTN) scheme? Yes No
• Under the Clinical Trial Exemption (CTX) scheme? Yes No
Clinical Trials Registry

• Is the clinical trial registered on a publicly accessible clinical trials registry database?   Yes  No

• If yes, please provide the name of the clinical trials registry and the study reference number.

• If no, please explain why the study is not registered on a publicly accessible clinical trials registry database.
Clinical Studies Indemnity and Insurance

• 14.1 Is the Medicines Australia Standard Indemnity Form(s), signed by the sponsor attached?
  Yes □ No □ N/A □

• 14.2 Is there evidence of adequate insurance cover attached?
  Yes □ No □ N/A □
15. Research Study Agreements

• List of available Agreements is unchanged

• Legal review of non-standard contracts
16. Intellectual Property

- There are no changes to this section.
17. Biosafety, Chemical & Radiation Safety

- Only change is to Australian Radiation Protection and Nuclear Safety question.

- Where state legislation requires it, the radiation safety approval AND registration is required.
18. Resource and Budget Information

• Only change is to “Site Finance Management”
• Current headings are:
  – Monetary cost for the site
  – $ Per patient costs
  – $ Funds source (Cost centre)
  – Cost covered by sponsor or funder (Y/N)
In the new SSA:

- Total monetary cost for the site /year
- In kind costs
- An indication of which costs are covered by the sponsor.
19. Funds Management Details

- Unchanged.
20. Qld Health Database of Research Activity.

- Series of boxes showing the information to be uploaded into “DORA”.
- Full and short titles
- Type of study
- HREC number
- Description of the project in plain language.
- NHMRC category
- Investigator AT THIS SITE
• Contact person at this site
• Funding source
• Anticipated start and finish dates
• Consent section:
  • I, the local site Principal Investigator, have the authority to give consent for the above details to be uploaded onto the Queensland Health Database of Research Activity
    Yes  No
  • I, the local site Principal Investigator, give consent for the above details for this site to be uploaded onto the Queensland Health Database of Research Activity
    Yes  No
  • Explanation required if consent not given.
Signatures

- Nothing new here.
- Just clarifying a few points!!!!
INTRODUCING THE AMAZING STUDY COORDINATOR DOLL

- Never needs batteries!
- Runs on coffee & chocolate!
- Works 60-80 hours a week!
- On an incredible 0.5 FTE!

"Do I have to report this to the IRB?"

"Where's my approval letter?"

Fun accessories:
- Fax machine
- Laptop
- Cell phone
- Top
- Anti-depressants

Caution: Not suitable for children under 35, as intense stress levels may pose psychological hazards.